REMARKS / ARGUMENTS

Further and favorable reconsideration of the subject application in light of the following remarks pursuant to and consistent with 37 C.F.R. § 1.111, are respectfully requested.

These remarks follow the interview of August 24, 2009. The interview substantially advanced examination of the application.

Substance of the Interview

During the interview, applicants discussed the support for the term uniform coating in reference to the polymer coating of the microcrystals of the active agent. The term has been rejected as lacking written description support. Applicants traverse the rejection. Applicants argued that, taken in context, one of ordinary skill in the art would have understood that microcrystals of active agent coated with a polymer as described in the instant specification (e.g, by fluidized bed coating), would have produced a continuous or uniform coating of the polymer. This imparts the desired taste-masking effect such that on disintegration of the tablet in the mouth, the patient is not subjected to unpleasant tastes associated with various active agents.

Without acceding to the rejection, but rather to expedite examination and more accurately recite the property described in the specification, applicants propose further amending the term to recite a *continuous polymer coating* on the surface of the particles of active agent. Entry of the amendment, further examination, and reconsideration of the outstanding rejection is respectfully requested.

Oury Declaration

The limitation requiring a continuous polymer coating on the surface of the particles of active agent is supported throughout the specification. As evidence of that support, submitted herewith is a declaration of Pascal Oury. Dr. Oury's declaration shows that the coating methods of the referenced specification produce active agent particles (microcrystals or microgranules) having a continuous polymer coating on the surface of the particles.

By resort to photomicrographs, Dr. Oury shows that microcrystalline paracetamol, when coated in a fluidized bed with about 10% polymer by weight of the coated particles, results in a particle having such a continuous coating. The coating protects and shields the active agent from dissolution in the mouth, thereby avoiding unpleasant taste sensation for the patient.

Dr. Oury further states that it would have been clear to one of ordinary skill in the art reading the referenced specification at the time of its filing that the addition of the polymer as described therein would have produced a continuous coating on the surface of the particles of active agent (e.g., microcrystals or microgranules). Thus, the specification supports the limitation of a particle of active agent having a continuous polymer coating on its surface.

The Invention

The claimed invention must be considered as a whole. Applicant wishes to emphasize that the coating of the microcrystals of active agent is not the sole, or even perhaps the most significant, inventive feature of the claimed invention. Rather, as is discussed throughout the specification, one of the principal advantages of the present invention is derived from the unexpected benefits from compounding the instant tablets such that at least a majority of the lubricant (for example, and without limitation, magnesium stearate) is positioned on the outer surface of the tablet. To the extent that there is any remaining lubricant that is not positioned on the exterior surface of the tablet, that may be disposed within the dry mix of the tablet. For example, in the paragraph bridging pages 1-2 of the specification, it is stated that "prior to compression [of the tablet] at least the greater part of the lubricating agent is no longer present in the mixture of excipients but is brought into contact with the outer surface of the mass that will form the subsequent tablet."

The specification further states that the invention is "characterized in that a major amount of the lubricating agent which is used in its composition and which is in powder form, is distributed on the tablet surface, and by the fact that its friability, ... is less than 1%, and preferably less than 0.5%." Specification, p. 2, lines 10-16.

Additionally, there is described a particular embodiment wherein the entire amount of the lubricating agent is distributed on the outer surface of the tablet. Specification, p. 2, lines 29-31.

To expedite examination, applicants propose amending the claims relative to those submitted in the Response of August 3, 2009, such that the microcrystals and microgranules have a continuous polymer coating. This comports more closely with the evidence of the Oury Declaration, and more accurately characterizes the resulting particles. That is, the polymer coating might not be entirely uniform in terms of its thickness; however, it is a continuous coating in that the entirety of the outer surface of a particle of active agent is coated with the polymer. Because, as shown by the Oury Declaration, this is what would have been expected by one of ordinary skill in the art at the time the invention was made, the limitation is supported by the specification. Accordingly, applicants request reconsideration and withdrawal of the written description rejection.

CONCLUSION

For at least the reasons set forth above, it is respectfully submitted that the above-identified application is in condition for allowance. Favorable reconsideration and prompt allowance of the claims are respectfully requested.

Should the Examiner believe that anything further is desirable in order to place the application in even better condition for allowance, the Examiner is invited to contact Applicant's attorney at the telephone number below.

The Director is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17 and 1.20(d) and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800.

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY PC

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